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Antimicrobial Efficacy of Multipurpose Disinfecting Solutions in the Presence of Contact Lenses and Lens Cases

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Objective: The aim of this study was to use antimicrobial efficacy endpoint methodology to determine compatibility of multipurpose disinfecting solutions (MPSS), lens cases, and hydrogel lenses for disinfection (AEEMC) against International Organization for Standardization (ISO)-specified microorganisms and clinical ocular isolates of *Stenotrophomonas maltophilia*.

Methods: Six MPSS (PQ/Aldox 1, 2, and 3; PQ/Alexidine; PQ/PHMB; and PHMB) were challenged against ISO-specified microorganisms and *S. maltophilia* using the AEEMC test. AEEMC tests were performed with and without balafilcon A, etafilcon A, and senofilcon A lenses in lens cases with organic soil. Exposure times included disinfection time (DT) and 24 hr. Additionally, all six MPSS were challenged with two strains of *S. maltophilia*, based on the ISO Stand-alone test.

Results: The efficacy against bacteria for PQ/Aldox and PQ/Alexidine MPSS was not diminished by the presence of lenses. The efficacy of PQ/PHMB and PHMB MPSS against *Serratia marcescens* was significantly reduced compared with the no-lens control at DT for at least one lens type. The PHMB MPSS with lenses present also demonstrated reduced efficacy against *Staphylococcus aureus* at DT versus the control. PQ/Aldox MPSS retained activity against *Fusarium solani* with lenses present; however, all other test MPSS demonstrated reduced *F. solani* efficacy at DT with lenses present. With lenses, all MPSS showed reduced efficacy against *Candida albicans*.

Conclusions: AEEMC antimicrobial efficacy test results vary based on challenge microorganism, contact lenses, and MPSS biocide systems. This study highlights the importance of evaluating MPSS for compatibility with lenses and lens cases.

Key Words: AEEMC—Disinfection—Contact lenses—Multipurpose solutions—Lens cases.

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Multipurpose disinfecting solutions (MPSS) are an essential part of maintaining hygiene for weekly or monthly replacement of soft contact lenses. Regulatory agencies require that MPSS

meet standard antimicrobial efficacy criteria to ensure they can effectively reduce microbial contamination introduced during lens insertion and lens removal, cleaning, and storage.

Regulatory approval of MPSS requires the demonstration of antimicrobial efficacy by fulfillment of the minimum requirements of the International Organization for Standardization (ISO) 14729 Stand-alone test.¹ This test evaluates the intrinsic microbial efficacy characteristics of any given MPSS but does not take into account potential interactions between the biocide and contact lenses, lens cases, or contaminating organic materials.²

Biocide uptake from MPSS by contact lenses has been demonstrated in multiple studies and has been shown to reduce antimicrobial efficacy.^{3–5} To address this issue and to better reflect consumer use of MPSS, the US Food and Drug Administration (FDA) proposed testing lens care products for interaction with contact lens materials and lens cases.^{2,6} In addition, ISO has developed a new standard, Ophthalmic Optics—Contact lens care products—Method to assess contact lens care products with contact lenses in a lens case, challenged with bacterial and fungal organisms (ISO 18259 [AEEMC test]),⁷ which takes into account the impact of biocide uptake by contact lenses and lens cases in the presence of organic soil.^{7–9}

We evaluated the effect of lenses, MPSS, and lens cases on the antimicrobial activities of six marketed MPSS (PQ/Aldox 1, 2, and 3; PQ/Alexidine; PQ/PHMB; and PHMB) against the ISO 14729-specified organisms. In addition, the antimicrobial efficacy of the six MPSS against *Stenotrophomonas maltophilia* was assessed. *S. maltophilia* is a Gram-negative bacterium that has been recovered from used contact lens cases of patients in whom bacterial keratitis has developed.^{10,11} Antimicrobial efficacy against *S. maltophilia* was determined using both the AEEMC and Stand-alone tests.

MATERIALS AND METHODS

Materials

Multipurpose Solutions

The six MPSS are described in Table 1. Each MPSS was used within its stated expiration date and tested according to its manufacturer's instructions for minimum disinfection time (DT).^{12–17}

Challenge Microorganisms

Microorganisms were obtained from the American Type Culture Collection (ATCC) or Alcon Microbial Culture Collection (MCC). The five ISO 14729-specified microorganisms were bacteria (*Staphylococcus aureus* ATCC 6538, *Pseudomonas aeruginosa* ATCC 9027, and *Serratia marcescens* ATCC 13880), yeast

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TABLE 1. Composition and Disinfection Time of Multipurpose Solutions for Contact Lenses¹²⁻¹⁷

| Abbreviation for the MPS Tested | Biocide Composition of MPS | Product | Disinfection Time, hr |
|---------------------------------|--|---|-----------------------|
| PQ/Aldox 1 | Polyquaternium-1 (0.001%), myristamidopropyl dimethylamine (0.0006%) | OPTI-FREE PureMoist Multi-Purpose Disinfecting Solution (Alcon Research, Ltd) | 6 |
| PQ/Aldox 2 | Polyquaternium-1 (0.001%), myristamidopropyl dimethylamine (0.0005%) | OPTI-FREE RepleniSH Multi-Purpose Disinfecting Solution (Alcon Research, Ltd) | 6 |
| PQ/Aldox 3 | Polyquaternium-1 (0.001%), myristamidopropyl dimethylamine (0.0005%) | OPTI-FREE EXPRESS Multi-Purpose Disinfecting Solution (Alcon Research, Ltd) | 6 |
| PQ/Alexidine | Polyquaternium-1 (0.0003%), alexidine dihydrochloride (0.00016%) | RevitaLens OcuTec Multi-Purpose Disinfecting Solution (Abbott Medical Optics) | 6 |
| PQ/PHMB | Polyquaternium (0.0001%), polyaminopropyl biguanide (0.00013%) | Biotrue Multi-Purpose Solution (Bausch & Lomb) | 4 |
| PHMB | Polyaminopropyl biguanide (0.0001%) | ReNu Fresh Multi-Purpose Solution (Bausch & Lomb) | 4 |

All solutions tested are available globally.

(*Candida albicans* ATCC 10231), and mold (*Fusarium solani* ATCC 36031). In addition, two ocular isolates of *S. maltophilia* (MCC 71391 and MCC 71003) were evaluated. Both *S. maltophilia* isolates were recovered from patients in conjunctivitis treatment studies. *Stenotrophomonas maltophilia* MCC 71391 is a multidrug-resistant isolate.

Contact Lenses and Lens Cases

Along with MPS manufacturer-supplied contact lens cases, three contact lens materials were used in the AEEMC test. These included two silicone hydrogel lens types representing group V lenses (balafilcon A, PureVision; Bausch & Lomb, Rochester, NY; and senofilcon A, ACUVUE OASYS; Vistacon/Johnson & Johnson Vision Care, Jacksonville, FL) and one hydrogel lens representing group IV lenses (etafilcon A, ACUVUE 2, Vistacon/Johnson & Johnson Vision Care).¹⁸ All lenses, solutions, and lens cases were new and unused before testing.

Study Design

The AEEMC test was performed to assess the interaction of three contact lens material types with six MPSs (Table 1) in their respective lens cases against five ISO 14729-specified microorganisms. Additional evaluation of the antimicrobial disinfection efficacy of six MPSs against two clinical ocular isolates of *S. maltophilia* was performed using both the AEEMC and Stand-alone tests.

The AEEMC study protocol was based on a previously published draft standard (2008)^{8,9} in which contact lenses and lens case combinations were incubated with microorganisms in the presence of various MPSs. The MPSs were matched with their manufacturer-supplied contact lens cases.

AEEMC Test

Microorganism suspensions of *S. aureus*, *P. aeruginosa*, *S. marcescens*, *C. albicans*, and *F. solani* were prepared at concentrations of 2.0×10^7 to 2.0×10^8 colony-forming units (CFU) per milliliter using a spectrophotometer and appropriate diluents. Each suspension was washed by centrifugation and resuspended in an organic soil solution (heat-killed *Saccharomyces cerevisiae* combined with heat-inactivated fetal bovine serum¹).

Three lens case wells were prepared for each type of lens, challenge organism, and incubation time point. Lenses were

aseptically removed from their sterile packaging, blotted to remove packaging solution, and placed inside a lens case concave side up. An aliquot from the challenge inoculum (100 μ L) was added to each lens. A contact time of 3 min was observed before adding MPS to the lens case. No-lens controls (MPS without lenses) and organism controls (diluent only) were prepared in the same manner. The final organism concentration in the lens wells was 2.0×10^5 to 2.0×10^6 CFU/mL. The cases were closed and incubated at $22.5^\circ\text{C} \pm 2^\circ\text{C}$.

Organism controls were evaluated at the beginning of the study to determine starting microbial load. Test samples and no-lens controls were evaluated at the manufacturer's recommended DT (i.e., 4 or 6 hr; Table 1) and 24 hr to determine remaining microbial load. Serial 1:10 dilutions were conducted in Dey Engley Neutralizing Broth (DE Broth). Triplicate pour plates were prepared from appropriate dilutions using soybean-casein digest agar containing neutralizers (0.07% lecithin and 0.5% polysorbate 80). Bacteria and yeast were incubated for 2 to 5 days at $32.5^\circ\text{C} \pm 2^\circ\text{C}$, whereas mold was incubated for 5 to 7 days at $22.5^\circ\text{C} \pm 2^\circ\text{C}$.

ISO 14729 Stand-alone Test

Microorganism suspensions of *S. maltophilia* MCC 71003 and MCC 71391 were prepared at concentrations of 1.0×10^7 to 1.0×10^8 CFU/mL using a spectrophotometer and appropriate diluents. One set of suspension was washed by centrifugation and resuspended in an organic soil solution (heat-killed *S. cerevisiae* combined with heat-inactivated fetal bovine serum¹). A second set of suspension was not washed and did not contain organic soil.

Three test tubes of appropriate material were prepared for each challenge organism and test MPS (10 mL). An aliquot from the challenge inoculum (100 μ L) was added to each tube. Organism controls were prepared in the same manner using appropriate diluents. The final organism concentration in the test samples and controls was 1.0×10^5 to 1.0×10^6 CFU/mL. The test samples were stored at $22.5^\circ\text{C} \pm 2^\circ\text{C}$.

Organism controls were evaluated at the beginning of the study to determine starting microbial load. Test samples were evaluated at the manufacturer's recommended DT (4 or 6 hr) to determine remaining microbial load. Serial 1:10 dilutions were conducted in DE Broth. Duplicate pour plates were prepared from appropriate dilutions using soybean-casein digest agar containing neutralizers

(0.07% lecithin and 0.5% polysorbate 80). Bacteria were incubated for 3 to 5 days at 32.5°C±2°C.

Calculations

Log reduction values were calculated as the difference between the log₁₀ count of surviving microorganisms at the specified exposure time to the MPS (DT or 24 hr) and the log₁₀ count of the starting organism count. Two-tailed independent *t* tests assuming Gaussian distributions were performed within each MPS testing group at each time point for individual lenses as compared with the no-lens control. *P* values less than 0.05 define statistical difference.

Test Criteria

There are no criteria for the AEEMC test.⁷ However, the objective of the method is to compare the efficacy of the no-lens control with that of the solutions containing contact lenses. Significant differences in efficacy between solutions containing lenses and the corresponding MPS no-lens control are an indication of pre-

servative uptake. The primary criterion of the ISO Stand-alone test is a mean reduction of not less than 99.9% (3.0 log reduction) in challenge bacteria by the recommended DT. For yeast and mold, a mean reduction not less than 90% (1.0 log reduction) by DT and no increase at 24 hr (>0.5 logs) is required.¹

RESULTS

AEEMC Test

Among the six MPSs, PQ/Aldox MPSs and PQ/Alexidine MPS, in the presence and absence of lenses, demonstrated greater than 4.0 log kill against *S. marcescens*, *S. aureus*, and *P. aeruginosa* at DT and 24 hr (Fig. 1A–F). However, when evaluated in the presence of lenses, PQ/PHMB MPS efficacy against *S. marcescens* was reduced significantly (*P*=0.0034) to 2.3 log kill for etafilcon A lenses compared with the no-lens control at DT (Fig. 1A). In the presence of the three lenses, the PHMB MPS demonstrated ≤2.5 log kill against *S. marcescens* at DT (Fig. 1A). Additionally, against *S. aureus*, the

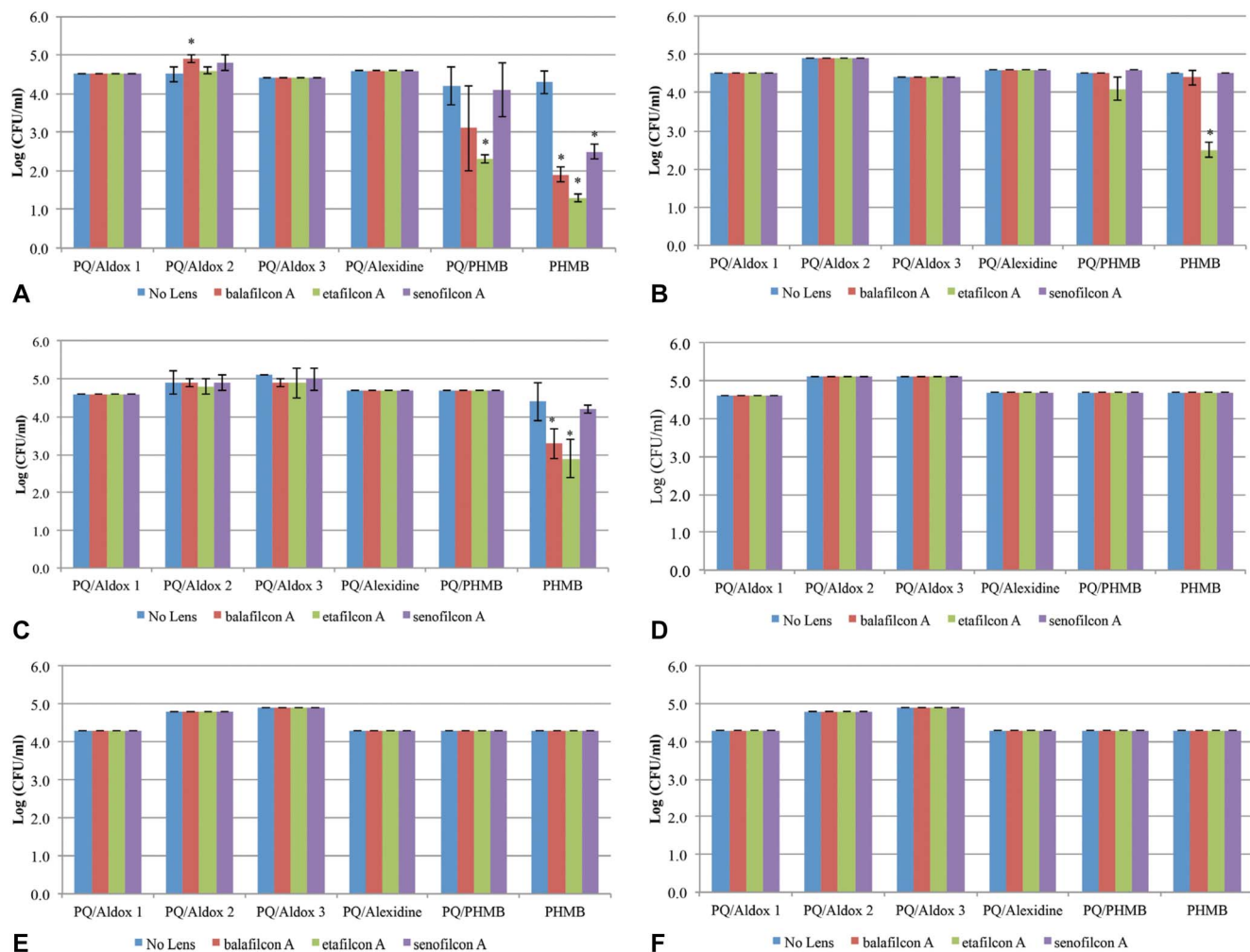


FIG. 1. Disinfection efficacy of 6 MPSs assessed using AEEMC test for challenge bacteria at disinfection time (DT) and 24 hr. (A) *Serratia marcescens* (DT); (B) *S. marcescens* (24 hr); (C) *Staphylococcus aureus* (DT); (D) *S. aureus* (24 hr); (E) *Pseudomonas aeruginosa* (DT); (F) *P. aeruginosa* (24 hr). Bars are standard deviations. *Log reductions with *P* values less than 0.05 as compared with the corresponding MPS no-lens controls are indicated. AEEMC, method to assess contact lens care products with contact lenses in a lens case, challenged with bacterial and fungal organisms; MPSs, multipurpose disinfecting solutions. [full color online](#)

PHMB MPS demonstrated a statistically significant reduction compared with the no-lens control (4.4 log kill) for balafilcon A and etafilcon A (3.3 log kill [$P=0.0484$] and 2.9 log kill [$P=0.0247$], respectively) at DT (Fig. 1C).

PQ/Aldox MPSs in the presence and absence of lenses demonstrated ≥ 4 log kill against *F. solani*, with the exception of PQ/Aldox 3 and etafilcon A lenses, which demonstrated a statistically significant reduction at DT compared with the no-lens control ($P=0.002$; Fig. 2A). PQ/Alexidine MPS efficacy against *F. solani* without lenses was 4.6 log kill at DT and 24 hr, but in the presence of all three lenses, efficacy was reduced to ≤ 2.3 log kill at DT and ≤ 3.5 log kill at 24 hr (Fig. 2A–B). In the absence of lenses, MPSs containing PQ/PHMB and PHMB demonstrated 1.6 and 1.2 log kills, respectively, against *F. solani* at DT (Fig. 2A). In the presence of lenses, PQ/PHMB MPS demonstrated a statistically significant reduction in efficacy against *F. solani* with balafilcon A ($P=0.0031$) and etafilcon A ($P=0.0030$) lenses at DT (Fig. 2A). PHMB MPS with lenses exhibited no difference in *F. solani* efficacy from the no-lens control at DT. However, the PHMB no-lens control demonstrated the lowest efficacy against *F. solani* (1.2 log kill) compared with the other MPSs (Fig. 2A–B).

The efficacy of the MPSs against *C. albicans*, when measured in the absence of lenses, varied considerably (Fig. 2C–D). PQ/Aldox 1, 2, and 3 MPSs demonstrated efficacy of 3.7, 4.7, and 4.4 log kills, respectively, against *C. albicans* at DT (Fig. 2C). Each of these MPSs also showed greater than 4.0 log kill at 24 hr without lenses (Fig. 2D). At DT, the PQ/Alexidine MPS demonstrated 2.4 log kill against *C. albicans*, PQ/PHMB 1.6 log kill, and PHMB MPS less than 1.0 log kill. Of these three MPSs, only

PQ/Alexidine MPS demonstrated greater than 4.0 log kill at 24 hr without lenses (Fig. 2D). In the presence of lenses, PQ/Aldox MPSs demonstrated efficacy against *C. albicans* of ≤ 1.6 log kill at DT (Fig. 2C). For all other MPSs in the presence of lenses, efficacy did not exceed 1.0 log kill at DT for any lens (Fig. 2C).

For the AEEMC testing of *S. maltophilia* clinical isolates, at DT, PQ/Aldox 1, PQ/Aldox 2, and PQ/PHMB demonstrated reduced efficacy of the MPS with lenses as compared with the no-lens control to a varying degree dependent on lens type and *S. maltophilia* strain, though the efficacy remained >3 log kill even in solutions with reduced efficacy. PQ/Aldox 3 and PHMB MPSs exhibited no differences in efficacy with both strains when comparing the no-lens control with solutions with all three lenses (Fig. 3A–D).

Stand-alone Test

Results from Stand-alone testing indicate that all the six MPSs challenged with *S. maltophilia* meet or exceed the primary criterion of the Stand-alone test, with >3.0 log kill (99.9% reduction) at DT. No differences in efficacy were observed for MPSs challenged with *S. maltophilia* MCC 71003 (in the presence or absence of organic soil) and MCC 71391 (in the absence of soil). PHMB and PQ/PHMB MPSs challenged with *S. maltophilia* MCC 71391 in the presence of soil demonstrated 3.1 and 3.4 log kills, respectively, whereas all other solutions exhibited >4.5 log kill (Table 2).

DISCUSSION

The AEEMC methodology was developed as a result of the 2006 *Fusarium* keratitis outbreak, which highlighted the need for

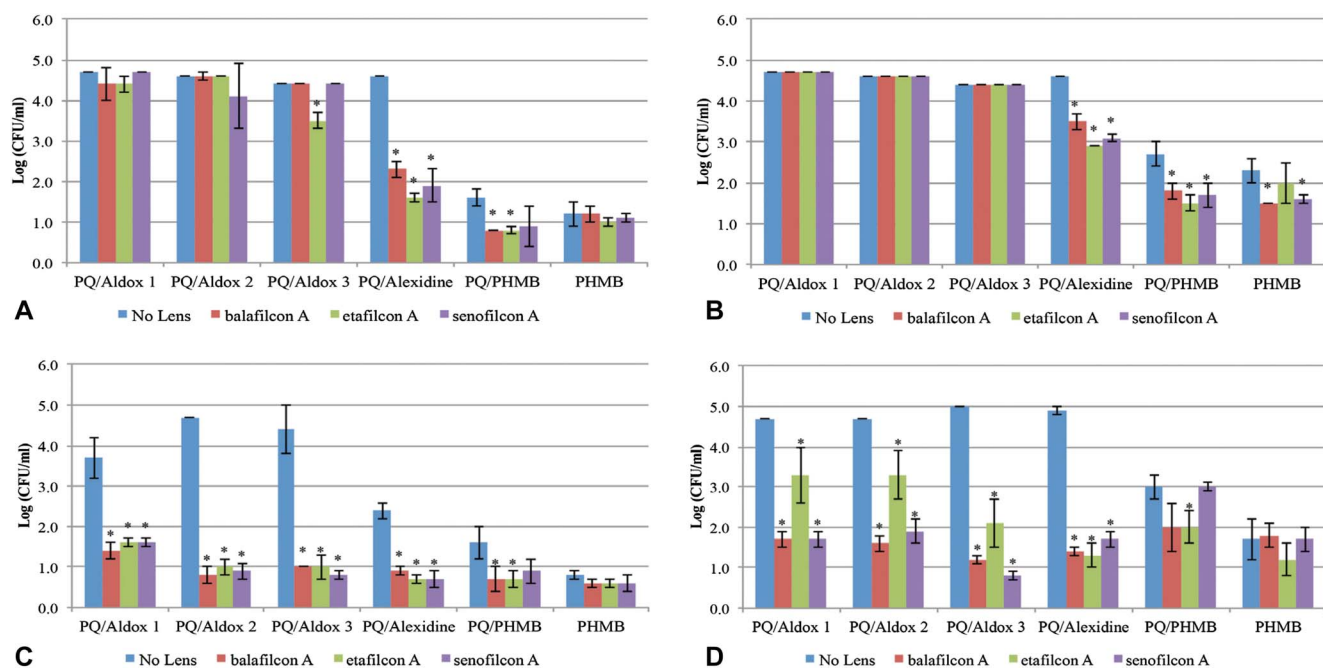
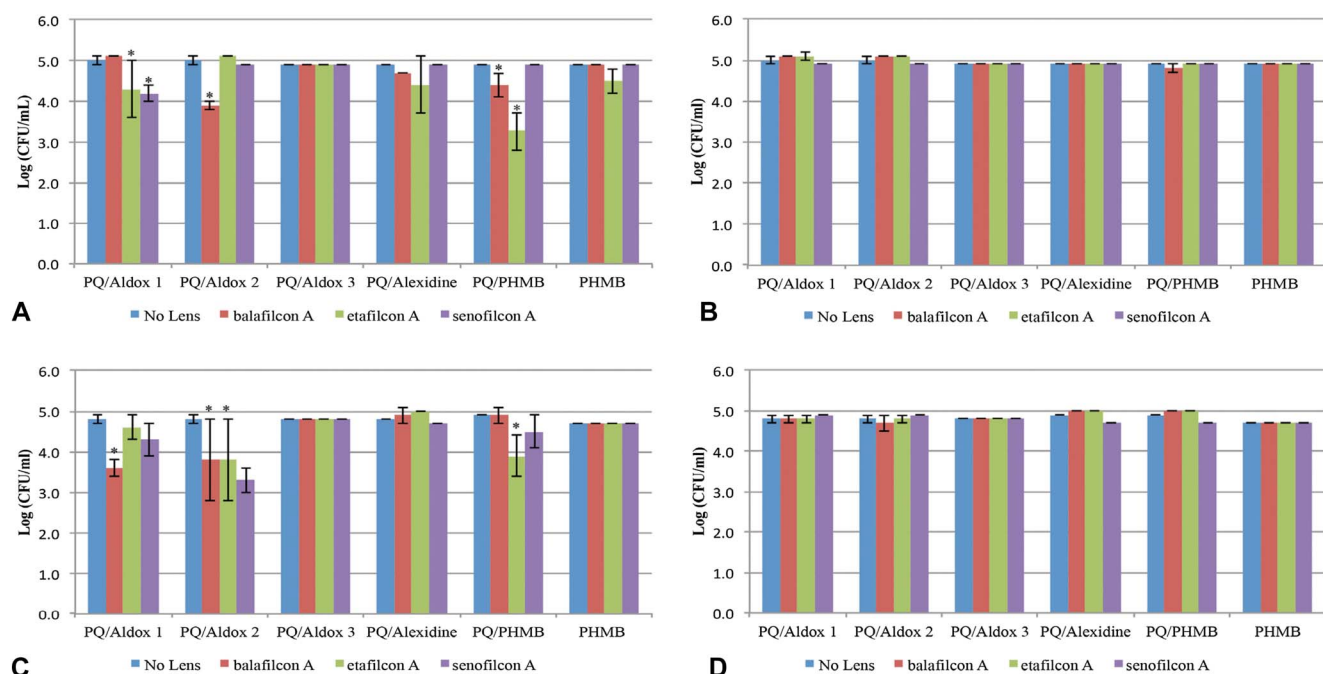


FIG. 2. Disinfection efficacy of 6 MPSs assessed using AEEMC test for challenge mold and yeast at disinfection time (DT) and 24 hr. (A) *Fusarium solani* (DT); (B) *F. solani* (24 hr); (C) *C. albicans* (DT); (D) *C. albicans* (24 hr). Bars are standard deviations. *Log reductions with P values less than 0.05 as compared with the corresponding MPS no-lens controls are indicated. AEEMC, method to assess contact lens care products with contact lenses in a lens case, challenged with bacterial and fungal organisms; MPSs, multipurpose disinfecting solutions. [full color online](#)



assessing the compatibility of contact lenses, lens cases, and contact lens care disinfecting solutions. Contact lens uptake of preservatives during disinfection was suspected to have reduced the efficacy of the recalled contact lens care solution.¹⁹ This is the first published study showing the impact of contact lenses on the disinfection efficacy of commercially available solutions since the development of the ISO AEEMC protocol.

We have demonstrated that the presence of contact lenses can reduce the antimicrobial efficacy of MPSs specific to the biocide system and challenge organism. For bacteria, the MPSs that were most affected by the presence of lenses were those solutions using PHMB. Solutions containing PHMB demonstrated a marked reduction in efficacy in the presence of etafilcon A lenses against *S. marcescens* at DT (Fig. 1A) and to a lesser extent for the PHMB-only solution against *S. aureus* at DT (Fig. 1C). MPSs with biocide systems consisting of PQ in combination with either Aldox or Alexidine demonstrated no reduction in efficacy between solutions containing all three lens types and the no-lens control for all bacteria. The reduction of efficacy in the presence of lenses for solutions containing PHMB may be the result of a relatively low PHMB starting concentration (1 ppm). At this concentration, any level of preservative uptake has a potential to significantly affect the antimicrobial activity of the residual biocide in the solution.

In Figure 2A, the difference in efficacy against *F. solani* between the no-lens controls and those containing contact lenses was greater for the MPS containing PQ/Alexidine, which exhibited a decrease in log kill of >2 log at DT (Fig. 2A). Little to no difference in efficacy was seen with all other biocide combinations (<1 log difference

between no-lens control and in the presence of the lens). However, it should be noted that the PQ/PHMB- and PHMB-based preservative systems demonstrated 1.6 and 1.2 log kills, respectively, in the no-lens controls, whereas the PQ-containing solutions exhibited greater than 4 log kill in the no-lens controls. The decrease in log kill of the PQ/Alexidine solution is in contrast to the PQ/Aldox solutions, in which there was no difference between the no-lens controls and the samples containing all three contact lens materials at DT (with the exception of etafilcon A and PQ/Aldox 3). The differences seen in efficacy between these MPSs may be a result of the differing PQ concentrations of the solutions. The PQ/Alexidine solution contains 3 ppm of PQ, whereas the PQ/Aldox solutions contain PQ at 10 ppm. Therefore, any reduction in PQ because of uptake by lens materials would be more likely to affect the efficacy of solutions with lower starting PQ concentrations.

The greatest effect of preservative uptake was observed when all solutions containing lenses were challenged with *C. albicans*. For most PQ-containing solutions, the efficacy against *C. albicans* was significantly reduced in the presence of lenses at DT. Efficacy against *C. albicans* in the PHMB-only solution was not significantly reduced by the presence of lenses; however, the no-lens control for this MPS demonstrated <1.0 log reduction at DT, whereas the PQ/Alexidine no-lens controls exhibited 2.4 log kill at DT and the PQ/Aldox solutions exhibited ≥3.7 log kill at DT (Fig. 2C).

In a retrospective review of 84 consecutive patients diagnosed with fungal keratitis at a single medical center in southeastern United States, the most common risk factor for fungal keratitis in the years 2005 to 2006 was contact lens wear (52% of patients).

TABLE 2. ISO 14729 Stand-alone Test Results for *Stenotrophomonas maltophilia* Evaluated in the Presence and Absence of Organic Soil

| <i>S. maltophilia</i> MCC 71003 | | | | |
|---------------------------------|------|------------------------------------|---------|-----|
| MPS | Soil | Log Reduction at Disinfection Time | | |
| | | Initial Count (Log) | Average | ±SD |
| PQ/Aldox 1 | – | 6.1 | 5.1 | 0.0 |
| | + | 5.9 | 4.9 | 0.2 |
| PQ/Aldox 2 | – | 5.9 | 4.9 | 0.0 |
| | + | 5.8 | 4.2 | 0.7 |
| PQ/Aldox 3 | – | 5.8 | 4.8 | 0.0 |
| | + | 5.5 | 4.4 | 0.1 |
| PQ/Alexidine | – | 5.9 | 4.9 | 0.0 |
| | + | 5.7 | 4.7 | 0.0 |
| PQ/PHMB | – | 5.9 | 4.9 | 0.0 |
| | + | 5.7 | 4.7 | 0.0 |
| PHMB | – | 5.9 | 4.8 | 0.1 |
| | + | 5.7 | 4.7 | 0.0 |

| <i>S. maltophilia</i> MCC 71391 | | | | |
|---------------------------------|------|------------------------------------|---------|-----|
| MPS | Soil | Log Reduction at Disinfection Time | | |
| | | Initial Count (Log) | Average | ±SD |
| PQ/Aldox 1 | – | 5.7 | 4.7 | 0.0 |
| | + | 5.7 | 4.7 | 0.0 |
| PQ/Aldox 2 | – | 5.7 | 4.7 | 0.0 |
| | + | 5.8 | 4.8 | 0.1 |
| PQ/Aldox 3 | – | 5.7 | 4.7 | 0.0 |
| | + | 5.6 | 4.6 | 0.0 |
| PQ/Alexidine | – | 6.0 | 5.0 | 0.0 |
| | + | 5.7 | 4.7 | 0.0 |
| PQ/PHMB | – | 6.0 | 5.0 | 0.0 |
| | + | 5.8 | 3.4 | 0.1 |
| PHMB | – | 6.0 | 5.0 | 0.0 |
| | + | 5.8 | 3.1 | 0.1 |

ISO, International Organization for Standardization; MCC, Microbial Culture Collection; MPS, multipurpose disinfecting solution; SD, standard deviation.

The most commonly isolated genus was *Fusarium* (41%), followed by *Candida* (14%).²⁰ Moreover, ocular infections associated with *C. albicans* are more likely to be associated with an underlying condition (previous corticosteroid use) and more often related to trauma than to contact lens wear.²¹ They also occur more often in cooler climates.²² In addition, biofilms on soft contact lenses contaminated with *Fusarium* but not *C. albicans* are less susceptible to several multipurpose solutions.²¹ Our demonstration of reduced efficacy against *C. albicans*, therefore, may be of lesser significance inasmuch as the incidence of fungal keratitis during lens wear remains much lower than for bacterial keratitis, and ocular infections associated with *C. albicans* are relatively uncommon.²¹

The AEEMC study results presented here are consistent with published preservative uptake data. Shoff et al.³ showed that some silicone hydrogel or soft hydrophilic contact lens materials interact with PHMB when soaked in a commercially available MPS (PHMB label concentration 0.0001%) for 6 to 168 hr. The study found that after soaking with lenses, the PHMB concentrations in the remaining solution as measured using high-performance liquid chromatography were reduced. These lowered PHMB concentrations were associated with a decrease in antimicrobial efficacy against *S. aureus*. Another study, reported by Clavet et al.⁴ demonstrated that PHMB uptake by contact lenses over time can reduce its concentration in the formulation and subsequently reduce the fungicidal activity of the MPS

against *F. solani*. With some lens types, a 6-hr soak in the MPS reduced the concentration of PHMB by more than half of the stated label concentration, and the longer the soaking time the greater the depletion of PHMB concentration.

Although it is difficult to make direct comparisons with the aforementioned studies because of variations in MPS brands and batches, lens types, soaking times, soaking volumes, and challenge microorganisms, all studies suggest that the presence of lenses and soaking times may affect the antimicrobial activity of MPSs. Such concerns have come to the attention of regulatory agencies. In May 2014, the FDA Ophthalmic Devices Panel of the Medical Devices Advisory Committee sought input on methods to more accurately test the effect of consumer use on efficacy.^{7,23} As a result of the advisory committee meeting and other published data demonstrating the negative effects on MPS efficacy by contact lenses and cases, the FDA has indicated that it will revise guidance documents to “further improve the safety of US contact lens users.”^{23,24}

In addition to testing the efficacy of MPSs in consumer use conditions against ISO-specified organisms, we have demonstrated the AEEMC method’s utility to assess MPS efficacy against clinical isolates of *S. maltophilia*. This species has been implicated in corneal infiltrative events, such as infectious keratitis, conjunctivitis, and endophthalmitis.^{10,11} The use of this organism demonstrated the suitability of the AEEMC test method to assess the efficacy of an MPS against clinically relevant organisms.

The conclusions from our current study can be applied only to balafilcon A, etafilcon A, and senofilcon A lenses, as not all contact lens materials interact with MPSs in the same way, and other lenses may, therefore, have a different impact on MPS antimicrobial efficacy.^{2,4,25}

Furthermore, the use of the AEEMC methodology demonstrated biocide-specific differences in disinfection efficacy of MPSs at DT and 24 hr when combined with several different contact lens types in manufacturer-recommended lens cases. Future work may include additional sample times at days 7 and 30 days as required per the ISO 18259:2014 standard.

In summary, it was shown that changes in efficacy can be observed between DT and 24 hr. Although the AEEMC test does not specify performance criteria, when used in combination with the ISO 14729 Stand-alone test, it provides a more robust assessment of efficacy for lens care solutions under conditions of consumer use.

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